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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,318	11/03/1998	W. MONTY REICHERT	2978.1US	5269

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT PAPER NUMBER

1641

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/185,318

Applicant(s)
Reichert et al

Examiner
Chris L. Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 26, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above, claim(s) 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 25-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by King et al.

King et al (U.S. Patent 5,633,724) discloses an apparatus for analyzing a target substance on a pixel array, particularly an array of pixels containing chemicals. The apparatus utilizes evanescent excitation to facilitate the simultaneous illumination of the entire array while minimizing background scattered light (col. 2, lines 62-67). The array can be placed inside a

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high-gain optical cavity that affords a significant advantage of evanescent excitation. The optical output from a miniature and structurally simple light source can be trapped inside the optical cavity and can thereby amplify the light intensity a thousand-fold. In this embodiment, evanescent excitation permits simple direct fluorescence collection (col. 3, lines 1-20). As shown in Figure 1, an optical detection system (120) is positioned directly over the array for direct detection of fluorescence. The disclosed apparatus can be used for chemical detection of microscopic properties, such as fluorescence or phosphorescence, of a sample or more specifically, of a target substance contained within a sample. Examples of target substance include nucleic acids (col. 3, line 62, to col. 4, line 3). The disclosed array supports a binding reagent specific for a target substance on sites referred to as pixels. Evanescent excitation is used to generate an optical signal that indicates the presence or absence of binding between fluorescently tagged target substance and the binding reagent on each pixel (col. 4, lines 34-67, and col. 6, lines 55-67). The array can be formed on total internal reflection (TIR) element such as a waveguide or an optical fiber (col. 9, lines 66-67). For the detection of DNA, the array contains a unique 8-mer in each of its pixels (col. 14, lines 60-67).

In response to this rejection, Applicants argue that the term “pixels” in King appears to be strictly limited to various points on a waveguide surface to which a confluent layer of capture molecules is secured. Applicants further argue that King lacks any express or inherent description that the “pixels” mentioned therein comprise “site-specifically immobilized” capture

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oligonucleotides, or capture oligonucleotides that have been immobilized to specific sites on a waveguide surface, as recited in independent claim 25.

Applicant's arguments have been considered but are not convincing. The term "pixel" in King refers to a point on the waveguide but Applicant's attention is directed to col. 14, lines 60-67 of King which states that for the detection of DNA, the array contains a unique 8-mer in each of its pixels. There is an 8-mer oligonucleotide at each pixel which is sufficient to anticipate the "plurality of capture oligonucleotides" recited in claim 25.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al in view of Squirrell.

See above for the teachings of King et al.

King et al differs from the instant invention in failing to teach the use of a "first coating" on the TIR element to indirectly bind nucleic acids to each pixel and the use of a fluorescently labeled complementary oligonucleotide as a detection reagent.

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See paper #10 for the teachings of Squirrell (U.S. Patent 5,750,337).

It would have been obvious to one of ordinary skill in the art to treat the TIR element of King et al with the reagents taught by Squirrell to provide a TIR element with a surface that contains glutaraldehyde for covalent attachment of oligonucleotides having aminoterminals because Squirrell shows it to be a conventional manner which to immobilize nucleic acids onto an optical fiber such as those used in the TIR element of King et al. Furthermore, the reagents of Squirrell provide for covalent attachment of the oligonucleotides to the surface of the optical fiber which is more reliable for retaining the oligonucleotides on the surface of the optical fiber than absorbing the oligonucleotides on the surface of the optical fiber.

While King et al refers to fluorescently labeling the analyte (i.e. nucleic acid) in col. 6, lines 66-67, King et al do not say how this is done. It would have been obvious to use fluorescently labeled complementary oligonucleotides as a detection reagent, as taught by Squirrell, for detection of target nucleic acids in the apparatus of King et al because the fluorescently labeled complementary oligonucleotides of Squirrell are specific for the target nucleic acid and thus provide for an accurate detection of the target nucleic acid.

In response to this rejection, Applicants argue that like King, Squirrell lacks any teaching or suggestion of providing a waveguide which includes site-specifically immobilized capture oligonucleotides on a surface thereof.

Applicant's arguments have been considered but are not convincing. First, Applicant's are arguing King and Squirrell individually which is improper for a 103 obviousness rejection. One

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cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Second, contrary to Applicant's argument, both King and Squirrell teach "site-specifically immobilized capture oligonucleotides". Both King and Squirrell teach immobilizing oligonucleotides on a waveguide surface. Each immobilized oligonucleotide is a "site-specifically immobilized capture oligonucleotide".

5. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over King et al in view of Wybourne et al.

See above for the teachings of King et al.

King et al differs from the instant invention in failing to teach the use of biotin as a means to immobilize oligonucleotides to a waveguide surface.

See paper #10 for the teachings of Wybourne et al (U.S. Patent 5,465,151)

It would have been obvious to one of ordinary skill in the art to use an avidin-biotin system, as taught by Wybourne et al, to immobilize oligonucleotides onto the waveguide of King et al because Wybourne et al shows it to be conventional in the art to exploit the high binding affinity of avidin for biotin as a means to immobilize oligonucleotides onto the surface of a waveguide such as those disclosed in King et al.

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In response to this rejection, Applicants argue that like King and Squirrel, Wybourne lacks any teaching or suggestion of providing a waveguide which includes site-specifically immobilized capture oligonucleotides on a surface thereof.

Applicant's arguments have been considered but are not convincing. First, Applicant's are arguing King and Wybourne individually which is improper for a 103 obviousness rejection. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Second, as set forth above, the pixels in King support an 8-mer oligonucleotide which is sufficient to read on site-specifically immobilized capture oligonucleotides of the instant invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

cchin/cc
February 4, 2003


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
2/4/03